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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,254	12/27/2000	Siamak Tabibzadeh	0152.00384	8450
23557	7590	04/14/2004	EXAMINER	
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION 2421 N.W. 41ST STREET SUITE A-1 GAINESVILLE, FL 326066669			PORTNER, VIRGINIA ALLEN	
			ART UNIT	PAPER NUMBER
			1645	
DATE MAILED: 04/14/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/674,254	TABIBZADEH, SIAMAK
<b>Examiner</b>	<b>Art Unit</b>	
Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 26 January 2004.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 41-80 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 70 is/are allowed.  
 6) Claim(s) 41-69 and 71-80 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
Paper No(s)/Mail Date _____ .	6) <input type="checkbox"/> Other: _____ .

## DETAILED ACTION

1. Claims 41-80 and new claims 81-85 are pending.
2. Claims 63, 72 and 73 have been amended.
3. Claim 70 is allowed
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Priority*

5. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

6. The earliest priority claimed in the original first paragraph of the first page of the Specification, under the heading "CROSS-REFERENCE TO RELATED APPLICATION", was not granted by the PCT searching Authority, as shown on the front of the published PCT Application WO99/55902. The priority granted the PCT Application, PCT/US99/09366, was only to provisional Application 60/083,418 and not to any other US Applications or provisional applications as asserted by Applicant.

7. The amendment of the first paragraph of the Instant Specification, submitted in October 20, 2000, did not cancel the priority claim not granted by the PCT searching authority.
8. The second paragraph page 1, reads:

"This application is a conversion of a United States Provisional Application filed April 29, 1998, Serial number 60/083,418. Continuation in Part of application Serial NO. 08/919,421 filed 8/27/97 which claims benefit of US Provisional Application No. 60/025,800 filed August 27, 1996."

The second sentence in this paragraph is an incomplete thought as a “.” period occurs after the recitation of the number: 60/083,418. The second thought presented is discontinuous with the first. Even if this portion of the paragraph were amended, the priority would not be granted as the PCT searching authority did not grant priority to the earliest application recited. The content

of the second sentence of this paragraph should be canceled as the Instant Specification has not and can not perfect the priority claimed as it was not granted by the PCT searching authority.

The instant Application was filed as a National Stage Application under 35 USC 371, not 37 CFR 1.111.

9. Prior acknowledgement of a claim to priority, not granted by the PCT searching authority is also not perfected or granted in the instant Application. The earliest priority date granted in the instant Application is to Provisional Application 60/083,418 filed April 29, 1998.

***Election/Restrictions***

10. Newly submitted claims 81-85 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the methods encompassed by new claims 81-85 recite a combination of claim limitations and components contained in compositions not previously considered on the record and are directed to methods that are independent and distinct based upon the difference of structure, function and biological effect of antibodies, antisense nucleic acids and coding nucleic acid sequences administered in vivo to a female, brought about by the components contained in the compositions relative to the recited intended use of increasing or decreasing fertility.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims <sup>81-85 are</sup> withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Rejections Withdrawn***

11. Claim 63 objected to because of the following informalities: for a mis-spelled word has been obviated through amendment of the claim to recite the correct spelling.

12. Claims 72-73 are no longer rejected under 35 USC 101, in light of the claims having been amended to recite a methods step that no longer reads on a natural process and is therefore directed to statutory subject matter.

***Rejections Maintained***

13. Claims 72-73 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record in paper number 24, as the composition is claimed based upon function only , and is not required to comprise any specific reagent components with the recited biological function.

14. Claims 41-69, 71 rejected under 35 U.S.C. 102(b) as being anticipated by Tabibzadeh et al is maintained for reasons of record in paper number 24.

15. Claims 74-80 rejected under 35 U.S.C. 103(a) as being unpatentable over Tabibzadeh et al (US Pat. 5,916,751). is maintained for reasons of record in paper number 24.

***Response to Arguments***

16. The rejection of claims 72-73 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is traversed on the grounds that the claims have been amended to recite the administration of a composition.

17. It is the position of the examiner that the composition of claims 72-73 is directed to the administration of any composition, and is not required to comprise a specific means for the accomplishment of the recited intended use of the methods. The rejection is maintained for reasons of record in paper number 24, as the composition administered is claimed based upon function only , and is not required to comprise any specific reagent components with the recited

biological function. The composition may be a non-specific composition that indirectly effects an increase or decrease in the level of expressed ebaF. The instantly claimed genus of compositions that comprise any component or components that may comprise a specific or non-specific reagent has not been so described in such a way that the person of skill in the art would recognize that Applicant was in possession of the instantly claimed genus of methods.

18. The rejection of claims 41-69, 71 under 35 U.S.C. 102(b) as being anticipated by Tabibzadeh et al (US Pat. 5,916,751). is traversed on the grounds that (US Pat. 5,916,751) is not prior art based upon Applicant's priority claim

19. It is the position of the examiner that Applicant's priority claim was not granted by the PCT searching authority and is therefore conferred in the instant Application as well. (US Pat. 5,916,751) is therefore appropriately applied as prior art. The rejection is maintained for reasons of record in paper number 24.

20. The rejection of claims 74-80 under 35 U.S.C. 103(a) as being unpatentable over Tabibzadeh et al (US Pat. 5,916,751) is traversed on the grounds that (US Pat. 5,916,751) is not prior art.

21. It is the position of the examiner that the earliest claimed priority has not been granted by either the PCT searching authority, nor the US-PTO. While the priority claimed is asserted to obviate the applied reference, the priority claim has not been granted, nor perfected, nor can it be perfected, as the instant Application was filed under 35 USC 371, and not 37 CFR 1.111. The rejections made of record are maintained as set forth in paper number 24, and the discussion of priority made of record herein..

**New Claim Limitations/New Grounds of Rejection**

***Claim Rejections - 35 USC § 112***

22. Claims 72 and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claimed methods administer any composition to a female mammal for the recited functional effect. The invention is not clearly, nor distinctly claimed, as what components are contained within the recited composition are not set forth in the claimed methods. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

23. Claims 49-51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 7 of U.S. Patent No. 6,294,662. Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed claim 7 is directed to a species of diagnostic tool, specifically “a probe for detecting the presence of ebaF nucleic acid in bodily samples” the diagnostic tool being a nucleic acid sequence shown in SEQ ID NO 1, that is a DNA, cDNA, RNA or mRNA molecule that anticipates the instantly claimed genus of diagnostic tools directed to a nucleic acid that screening means for the presence of an ebaF nucleic acid, a screening means that specifically hybridized with ebaF nucleic acid, and a screening means that is a nucleic acid that specifically hybridizes with ebaF mRNA . The instantly claimed invention is directed to a genus of nucleic

acids that will detect ebaF in a sample and the allowed claims are directed to specific species of diagnostic tool which have a specific sequence shown in SEQ ID NO 1. A species anticipates the claimed genus; a genus claim is obvious over a species.

24. Claim 72 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,5,14 and 15 of U.S. Patent No. 6,649,588. Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed claim 15 is directed to specific species of methods for increasing the fertility of a female animal, through administering a specific species of composition to decrease the level of expression of ebaF in the infertile female with the fertility associated species of condition recited in allowed claim 15, and the instantly claimed genus of methods for increasing the fertility of female through administering any type of composition that is effective in increasing the fertility of the female mammal, wherein the allowed method increases the fertility in a female mammal that evidence specific species of condition associated with infertility; therefore, the allowed species anticipate the instantly claimed genus of methods associated with treating any condition with any composition. The instantly claimed invention is directed to a genus of methods and the allowed claims are directed to specific species of methods. A species anticipates the claimed genus; a genus claim is obvious over a species.

***Conclusion***

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on 7:30-5:00 M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp  
April 7, 2004

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